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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,608	08/10/2007	Dirk Mertin	BHC 031082	8795

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EXAMINER	
KENNEDY, NICOLETTA	
ART UNIT	PAPER NUMBER
4131	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/585,608	MERTIN ET AL.	
	Examiner	Art Unit	
	NICOLETTA KENNEDY	4131	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Miller et al. (US 5,122,377). With regard to claim 1, the claimed invention is for a pharmaceutical preparation for use in animals which is applied to the coat or the skin of the animal and which the latter then takes up orally. With regard to claim 10, applicants claim a method for applying such a compound.

Miller et al. teach a composition for oral delivery of veterinary medication where the product can be administered orally by inducing the animal to lick a dispensed quality from a surface, such as the animal's paw (Column 7, lines 31-35 and lines 47-48). The composition contains an active ingredient, such as amoxicillin, which is taken up orally by the animal (Column 7, lines 46-48 and column 8, lines 1-3). Each and every limitation of claims 1 and 10 is present in Miller et al.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-2 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over an invention in public use in this country, more than one year prior to the date of application for Patent in the United States, read in light of Miller et al.

With regard to claim 1, the claimed invention is for a pharmaceutical preparation for use in animals which is applied to the coat or the skin of the animal and which the latter then takes up orally. Claim 2 directs the preparation to use in cats. With regard to claim 10, applicants claim a method for applying such a compound to animals.

Hairball remedies targeted to cats, dogs, rabbits, and other mammals have been in use in the United States since at least 2002 (*See* FDA September/October 2002 newsletter, available at http://www.fda.gov/cvm/Documents/SeptOct.pdf). One such example of a hairball remedy is Hartz Advanced Care Hairball Remedy (first used in commerce in 2003). This product is directed to cats and rabbits and the directions for use include applying the preparation to the pet's front paws where it can be licked off readily (*See* Drugs.com Veterinary Edition, available at http://www.drugs.com/vet/hartz-advanced-care-hairball-remedy.html).

The hairball remedy differs from the claimed inventions because it teaches a non-medicated preparation. Miller et al., does though, teach a composition applied to the paw of an animal which the animal then takes up orally, that contains amoxicillin. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a medicine or drug in the composition with a reasonable expectation of success.

7. Claims 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watts et al. (US 6,191,143 B1) read in light of Miller et al. (US 5,122,377). Watts et al. teach a method of topically administering an antimicrobial agent such as enrofloxacin or a pharmaceutically acceptable salt thereof in liquid form to mammals (Summary of Invention, column 1, lines 55-65, and column 4, lines 13-14 and formula V).

With regard to claim 3, Watts et al. teach the topical or oral application of a composition by means of drops, spray, paint, or pour on; indicating that the composition is in liquid form (Column 5, lines 13-15). Miller et al. teach applying a composition to an

animal's paw which the animal then licks off of its paw (Column 7, lines 31-35 and lines 47-48). As Watts et al. and Miller et al. are in analogous arts and both contemplate topical and/or oral application of a medication, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply a composition in *liquid form* to an animal's coat or skin which the animal will then take up orally, with a reasonable expectation of success.

With regard to claim 5, Watts et al. differ from the claimed invention because they do not specifically teach application of the composition to the coat or skin of an animal. Watts et al. teach a method of topically administering an antimicrobial agent such as enrofloxacin or a pharmaceutically acceptable salt thereof in liquid form to mammals (Summary of Invention, column 1, lines 55-65, and column 4, lines 13-14 and formula V). Miller et al. teach the method of inducing an animal to groom itself by applying a composition to its paw.

Again, Watts et al. and Miller et al. are in analogous arts and both contemplate topical and/or oral application of a medication to an animal. Therefore, reading Watts et al. in light of Miller et al., it would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply a composition containing enrofloxacin or a pharmaceutically acceptable salt thereof to the coat or skin of the animal which the latter then takes up orally, with a reasonable expectation of success.

8. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Endler et al. (WO 01/08682 A2) in light of Miller et al. Endler et al. teach the use of flupirtine or its salt, administered orally, for the treatment of pain in cats and dogs (Specification).

Although Endler et al. does not teach the topical application of the composition which the animal then takes up orally, Miller et al. does teach applying a composition to an animal's paw which the animal then licks off of its paw (Column 7, lines 31-35 and lines 47-48).

Endler et al. and Miller et al. are in analogous arts and both contemplate the oral administration of medication for animals. Therefore, reading Endler et al. in light of Miller et al, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply a pharmaceutical preparation comprising flupirtine or its salts to an animal's coat or skin which the animal will then take up orally.

9. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mertin et al. (US 2006/0177414 A1) in light of Miller et al. Mertin et al. teach the use of pradofloxacin or its salt, administered orally, for administration to animals (para. 1 and examples 1-6 and 8-10). Although Mertin et al. does not teach the topical application of the composition which the animal then takes up orally, Miller et al. does teach applying a composition to an animal's paw which the animal then licks off of its paw (Column 7, lines 31-35 and lines 47-48).

Mertin et al. and Miller et al. are in analogous arts and both contemplate the oral administration of medication for animals. Therefore, reading Mertin et al. in light of Miller et al, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply a pharmaceutical preparation comprising pradofloxacin or its salts to an animal's coat or skin which the animal will then take up orally.

10. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hundley et al. (US 6,465,460) in light of Miller et al. Hundley et al. teach the use of toltrazuril or its salt, administered orally, for the prevention and treatment of protozoal disease in animals (Field Of the Invention and claims 1 and 4). Although Hundley et al. does not teach the topical application of the composition which the animal then takes up orally, Miller et al. does teach applying a composition to an animal's paw which the animal then licks off of its paw (Column 7, lines 31-35 and lines 47-48).

Hundley et al. and Miller et al. are in analogous arts and both contemplate the oral administration of medication for animals Therefore, reading Hundley et al. in light of Miller et al, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply a pharmaceutical preparation comprising toltrazuril or its salts to an animal's coat or skin which the animal will then take up orally.

11. Claims 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Spiegeleer et al. (US 2006/0240049 A1). De Spiegeleer et al. teach the oral administration of toltrazuril or its salts or ponazuril or its salts for the treatment of prevention of protozoal infections in animals (Abstract and para. 9).

Although De Spiegeleer et al. does not teach the topical application of the composition which the animal then takes up orally, Miller et al. does teach applying a composition to an animal's paw which the animal then licks off of its paw (Column 7, lines 31-35 and lines 47-48).

De Spiegeleer et al. and Miller et al. are in analogous arts and both contemplate the oral administration of medication for animals Therefore, reading De Spiegeleer et al.

in light of Miller et al, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply a pharmaceutical preparation comprising toltrazuril or its salts or ponazuril or its salts to an animal's coat or skin which the animal will then take up orally.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLETTA KENNEDY whose telephone number is (571)270-1343. The examiner can normally be reached on Monday through Thursday 6:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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